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PFIZER INC., PHARMACIA CORPORATION
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

NETRA THOMAS,
Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE LLC and MONSANTO
COMPANY,
Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-02110-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company¹) ("Pharmacia") and

¹ Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was

G.D. Searle LLC (“Searle”) and file this Answer to Plaintiff’s Complaint (“Complaint”), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Celebrex® (celocoxib) (“Celebrex®”). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Celebrex®.

II.

ORIGINAL ANSWER

Response to Allegations Regarding Parties

Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny that Plaintiff is entitled to any relief or damages. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s age or state of residence and, therefore, deny the same.

Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants state that the remaining allegations in this paragraph of the Complaint assert legal contentions to which no response is required. To the extent that a response is

incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed Celebrex®. Given that Plaintiff alleges in the Complaint that Monsanto Company was involved in distributing Celebrex®, *see* PLAINTIFF’S COMPLAINT at ¶ 7, Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

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1 deemed required, Defendants deny the remaining allegations in this paragraph of the Complaint.

2 Defendants admit that Pfizer is a Delaware corporation with its principal place of
3 business in New York. Defendants admit that Pfizer is registered to do business in the State of
4 Minnesota. Defendants admit that Pfizer may be served through its registered agent. Defendants
5 admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003,
6 Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain
7 periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United
8 States, including Minnesota, to be prescribed by healthcare providers who are by law authorized
9 to prescribe drugs in accordance with their approval by the FDA. Defendants state that
10 Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants
11 are without knowledge or information to form a belief as to the truth of such allegations, and,
12 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the
13 Complaint.

14 Defendants admit that Searle is a Delaware limited liability company with its principal
15 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,
16 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
17 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
18 packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex®
19 in the United States to be prescribed by healthcare providers who are by law authorized to
20 prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining
21 allegations in this paragraph of the Complaint.

22 Defendants admit that Pharmacia is a Delaware corporation with its principal place of
23 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
24 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
25 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted
26 Celebrex® in the United States to be prescribed by healthcare providers who are by law
27 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny
28 the remaining allegations in this paragraph of the Complaint.

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1 Defendants admit that in 1933 an entity known as Monsanto Company (“1933
2 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of
3 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to
4 Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was
5 incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed
6 its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged in the
7 agricultural business and does not and has not ever manufactured, marketed, sold, or distributed
8 Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle or
9 Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or
10 distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a proper party in
11 this matter. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 Defendants state that the response to this paragraph of the Complaint regarding Monsanto is
13 incorporated by reference into Defendants’ responses to each and every paragraph of the
14 Complaint referring to Monsanto and/or Defendants.

15 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and
16 co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
17 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
18 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
19 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
20 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
21 accordance with their approval by the FDA. Defendants admit that Pharmacia acquired Searle in
22 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries
23 of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

24 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and
25 co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
26 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
27 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
28 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States

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1 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
2 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe
3 and effective when used in accordance with its FDA-approved prescribing information.
4 Defendants state that the potential effects of Celebrex® were and are adequately described in its
5 FDA-approved prescribing information, which was at all times adequate and comported with
6 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
7 remaining allegations in this paragraph of the Complaint.

8 Defendants state that the allegations in this paragraph of the Complaint regarding
9 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
10 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the
11 same. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of
13 Minnesota. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of
15 Minnesota. Defendants are without knowledge sufficient to form a belief as to the allegations in
16 this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny the
17 same. However, Defendants admit that Plaintiff claims the amount in controversy satisfies the
18 jurisdictional amount of this Court. Defendants deny the remaining allegations in this paragraph
19 of the Complaint.

20 **Response to Factual Allegations**

21 Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s medical condition
23 or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that
24 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
25 prescribing information. Defendants state that the potential effects of Celebrex® were and are
26 adequately described in its FDA-approved prescribing information, which was at all times
27 adequate and comported with applicable standards of care and law. Defendants deny that
28 Celebrex® caused Plaintiff injury or damages and deny the remaining allegations in this

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1 paragraph of the Complaint.

2 Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
4 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
5 effective when used in accordance with its FDA-approved prescribing information. Defendants
6 state that the potential effects of Celebrex® were and are adequately described in its FDA-
7 approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
9 Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this
10 paragraph of the Complaint.

11 Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
13 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,
14 Celebrex® was expected to reach users and consumers without substantial change from the time
15 of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
23 remaining allegations in this paragraph of the Complaint.

24 Defendants state that the allegations in this paragraph of the Complaint regarding aspirin,
25 naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is
26 required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as
27 being a non-steroidal anti-inflammatory (“NSAID”) drugs. Defendants deny the remaining
28 allegations in this paragraph of the Complaint.

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1 Defendants state that the allegations in this paragraph of the Complaint are not directed
2 toward Defendants and, therefore, no response is required. To the extent that a response is
3 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
4 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
5 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

6 Defendants state that the allegations in this paragraph of the Complaint are not directed
7 toward Defendants and, therefore, no response is required. To the extent that a response is
8 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
9 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
10 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

11 Defendants state that the allegations in this paragraph of the Complaint are not directed
12 toward Defendants and, therefore, no response is required. To the extent that a response is
13 deemed required, Defendants state that Plaintiff fails to provide the proper context for the
14 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information
15 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

16 Defendants state that the allegations in this paragraph of the Complaint are not directed
17 toward Defendants and, therefore, no response is required. To the extent a response is deemed
18 required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he
19 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
20 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
21 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to
22 provide the proper context for the remaining allegations in this paragraph and Defendants
23 therefore lack sufficient information or knowledge to form a belief as to the truth of the
24 allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

25 Defendants state that the allegations in this paragraph of the Complaint regarding
26 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or
27 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the
28 same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he

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1 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,
2 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in
3 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state
4 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
5 prescribing information. Defendants state that the potential effects of Celebrex® were and are
6 adequately described in its FDA-approved prescribing information, which was at all times
7 adequate and comported with applicable standards of care and law. Defendants deny any
8 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

9 Defendants admit that Searle submitted a New Drug Application (“NDA”) for Celebrex®
10 on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of
11 Celebrex® for the following indications: (1) for relief of the signs and symptoms of
12 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.
13 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to
14 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (“FAP”)
15 as an adjunct to usual care (e.g., endoscopic surveillance surgery). Defendants deny the
16 remaining allegations in this paragraph of the Complaint.

17 Defendants admit that Celebrex® was launched in February 1999. Defendants admit
18 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex®
19 in the United States to be prescribed by healthcare providers who are by law authorized to
20 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during
21 certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed,
22 tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by
23 healthcare providers who are by law authorized to prescribe drugs in accordance with their
24 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used
25 in accordance with its FDA-approved prescribing information. Defendants state that the
26 potential effects of Celebrex® were and are adequately described in its FDA-approved
27 prescribing information, which was at all times adequate and comported with applicable
28 standards of care and law. Defendants deny any wrongful conduct and deny the remaining

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1 allegations in this paragraph of the Complaint.

2 Defendants state that the referenced article speaks for itself and respectfully refer the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 Defendants state that the referenced article speaks for itself and respectfully refer the
6 Court to the article for its actual language and text. Any attempt to characterize the article is
7 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 Defendants state that the referenced FDA Update speaks for itself and respectfully refer
9 the Court to the FDA Update for its actual language and text. Any attempt to characterize the
10 FDA Update is denied. Defendants deny the remaining allegations in this paragraph of the
11 Complaint.

12 Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny the allegations in this paragraph of the Complaint.

17 Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
22 the Complaint.

23 Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on
24 June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to
25 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,
26 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself
27 and respectfully refer the Court to the study for its actual language and text. Any attempt to
28 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of

1 the Complaint.

2 Defendants state that the referenced article speaks for itself and respectfully refer the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 Defendants state that the referenced study speaks for itself and respectfully refer the
6 Court to the study for its actual language and text. Any attempt to characterize the study is
7 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
8 paragraph of the Complaint.

9 Defendants state that the referenced Medical Officer Review speaks for itself and
10 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
11 attempt to characterize the Medical Officer Review is denied. Defendants state that the
12 referenced study speaks for itself and respectfully refer the Court to the study for its actual
13 language and text. Any attempt to characterize the study is denied. Defendants deny the
14 remaining allegations in this paragraph of the Complaint.

15 Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee
16 hearings speak for themselves and respectfully refer the Court to the transcripts for their actual
17 language and text. Any attempt to characterize the transcripts is denied. Defendants state that
18 the referenced study speaks for itself and respectfully refer the Court to the study for its actual
19 language and text. Any attempt to characterize the study is denied. Defendants deny the
20 remaining allegations in this paragraph of the Complaint.

21 Defendants state that the referenced articles speak for themselves and respectfully refer
22 the Court to the articles for their actual language and text. Any attempt to characterize the
23 articles is denied. Defendants state that the referenced study speaks for itself and respectfully
24 refer the Court to the study for its actual language and text. Any attempt to characterize the
25 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 Defendants state that the referenced article speaks for itself and respectfully refer the
27 Court to the article for its actual language and text. Any attempt to characterize the article is
28 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 Defendants state that the referenced articles speak for themselves and respectfully refer
2 the Court to the articles for their actual language and text. Any attempt to characterize the
3 articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants state that the referenced study speaks for itself and respectfully refer the
7 Court to the study for its actual language and text. Any attempt to characterize the study is
8 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

9 Defendants state that the referenced Medical Officer Review speaks for itself and
10 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
11 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
12 allegations in this paragraph of the Complaint.

13 Plaintiff fails to provide the proper context for the allegations concerning “Public
14 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
15 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 Defendants state that the referenced article speaks for itself and respectfully refer the
18 Court to the article for its actual language and text. Any attempt to characterize the article is
19 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 Defendants state that the referenced study speaks for itself and respectfully refer the
21 Court to the study for its actual language and text. Any attempt to characterize the study is
22 denied. Plaintiff fails to provide the proper context for the allegations concerning “Public
23 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or
24 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
25 Defendants deny the remaining allegations in this paragraph of the Complaint.

26 Defendants admit that there was a clinical trial called APC. Defendants state that the
27 referenced article speaks for itself and respectfully refer the Court to the article for its actual
28 language and text. Any attempt to characterize the article is denied. Defendants deny the

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1 remaining allegations in this paragraph of the Complaint.

2 Defendants state that the referenced article speaks for itself and respectfully refer the
3 Court to the article for its actual language and text. Any attempt to characterize the article is
4 denied. Plaintiff fails to provide the proper context for the allegations concerning “Data Safety
5 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient
6 information or knowledge to form a belief as to the truth of such allegations and, therefore, deny
7 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 Defendants state that the referenced article speaks for itself and respectfully refer the
9 Court to the article for its actual language and text. Any attempt to characterize the article is
10 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

11 Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
12 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
13 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
14 Defendants deny the remaining allegations in this paragraph of the Complaint.

15 Defendants state that the referenced Medical Officer Review speaks for itself and
16 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
17 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
18 allegations in this paragraph of the Complaint.

19 Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide
20 the proper context for the allegations concerning “other Celebrex trials” contained in this
21 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
22 form a belief as to the truth of such allegations and, therefore, deny the same. As for the
23 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state that
24 the referenced study speaks for itself and respectfully refer the Court to the study for its actual
25 language and text. Any attempt to characterize the study is denied. Defendants deny the
26 remaining allegations in this paragraph of the Complaint.

27 Defendants state that the referenced article speaks for itself and respectfully refer the
28 Court to the article for its actual language and text. Any attempt to characterize the article is

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1 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 Plaintiff fails to provide the proper context for the allegations regarding Merck and
3 Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or
4 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.
5 Defendants state that the referenced studies speak for themselves and respectfully refer the Court
6 to the studies for their actual language and text. Any attempt to characterize the studies is
7 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 Defendants state that the referenced Medical Officer Review speaks for itself and
9 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any
10 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining
11 allegations in this paragraph of the Complaint.

12 Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint
13 are not directed toward Defendants, and therefore no response is required. To the extent that a
14 response is deemed required, Plaintiff fails to provide the proper context for the allegations
15 regarding Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient
16 information or knowledge to form a belief as to the truth of such allegations and, therefore, deny
17 the same. Defendants state that the referenced study speaks for itself and respectfully refer the
18 Court to the study for its actual language and text. Any attempt to characterize the study is
19 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
21 Complaint are not directed toward Defendants, and therefore no response is required. To the
22 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
23 allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
24 therefore lack sufficient information or knowledge to form a belief as to the truth of such
25 allegations and, therefore, deny the same. Defendants state that the referenced study speaks for
26 itself and respectfully refer the Court to the study for its actual language and text. Any attempt
27 to characterize the study is denied. Defendants deny the remaining allegations in this paragraph
28 of the Complaint.

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1 Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the
2 Complaint are not directed toward Defendants, and therefore no response is required. To the
3 extent that a response is deemed required, Plaintiff fails to provide the proper context for the
4 allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants
5 therefore lack sufficient information or knowledge to form a belief as to the truth of such
6 allegations and, therefore, deny the same. Defendants state that the referenced study speaks for
7 itself and respectfully refer the Court to the study for its actual language and text. Any attempt
8 to characterize the study is denied. Defendants state that the referenced article speaks for itself
9 and respectfully refer the Court to the article for its actual language and text. Any attempt to
10 characterize the article is denied. Defendants deny the remaining allegations in this paragraph of
11 the Complaint.

12 Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants deny the allegations in this
14 paragraph of the Complaint.

15 Defendants state that the referenced article speaks for itself and respectfully refer the
16 Court to the article for its actual language and text. Any attempt to characterize the article is
17 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

18 Defendants state that allegations in this paragraph of the Complaint are not directed
19 toward Defendants, and therefore no response is required. To the extent that a response is
20 deemed required, Defendants state that the referenced article speaks for itself and respectfully
21 refer the Court to the article for its actual language and text. Any attempt to characterize the
22 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

23 Defendants deny the allegations in this paragraph of the Complaint.

24 Defendants state that Celebrex® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the

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1 remaining allegations contained in this paragraph of the Complaint.

2 Defendants deny any wrongful conduct and deny the remaining allegations contained in
3 this paragraph of the Complaint.

4 Defendants deny any wrongful conduct and deny the remaining allegations contained in
5 this paragraph of the Complaint.

6 Defendants state that Celebrex® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.

10 Defendants deny any wrongful conduct and deny the remaining allegations contained in this
11 paragraph of the Complaint.

12 Defendants are without knowledge or information sufficient to form a belief as to the
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
14 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
15 effective when used in accordance with its FDA-approved prescribing information. Defendants
16 state that the potential effects of Celebrex® were and are adequately described in its FDA-
17 approved prescribing information, which was at all times adequate and comported with
18 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
19 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of
20 the Complaint.

21 Defendants admit that the FDA Division of Drug Marketing, Advertising, and
22 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and
23 November 14, 2000. Defendants state that the referenced letters speak for themselves and
24 respectfully refer the Court to the letters for their actual language and text. Any attempt to
25 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph of
26 the Complaint.

27 Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.
28 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the

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1 letter for its actual language and text. Any attempt to characterize the letter is denied.

2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 Defendants state that the referenced article speaks for itself and respectfully refer the
4 Court to the article for its actual language and text. Any attempt to characterize the article is
5 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

6 Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.
7 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the
8 letter for its actual language and text. Any attempt to characterize the letter is denied.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
15 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
16 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
17 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
18 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
19 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
20 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
21 paragraph of the Complaint.

22 Defendants state that Celebrex® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
27 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
28 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants

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1 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
2 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
3 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
4 accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription
5 medication which is approved by the FDA for the following indications: (1) for relief of the signs
6 and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis
7 in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary
8 dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
9 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery);
10 (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and
11 symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants
12 deny any wrongful conduct and deny the remaining allegations in this paragraph of the
13 Complaint.

14 Defendants state that Celebrex® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which at all times was adequate and comported with applicable standards of care and law.
18 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
19 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
20 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
21 that Celebrex® is defective, and deny the remaining allegations in this paragraph of the
22 Complaint.

23 Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
28 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by

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1 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
2 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
3 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
4 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
5 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
6 paragraph of the Complaint.

7 Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which at all times was adequate and comported with applicable standards of care and law.
11 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
12 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
13 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
14 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
16 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
18 paragraph of the Complaint.

19 Defendants state that Celebrex® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Celebrex® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
2 the Complaint.

3 Defendants deny the allegations in this paragraph of the Complaint.

4 Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.

8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 Defendants state that Celebrex® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.

14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint.

16 Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
18 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
19 Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this
20 paragraph of the Complaint.

21 Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.

25 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
26 remaining allegations in this paragraph of the Complaint.

27 Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® are and were adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint.

5 Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® are and were adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants state that the referenced study speaks for itself and respectfully refer the Court to the
10 study for its actual language and text. Any attempt to characterize the study is denied.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 Defendants deny any wrongful conduct and deny the remaining allegations in this
14 paragraph of the Complaint.

15 Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
17 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 state that the potential effects of Celebrex® are and were adequately described in its FDA-
20 approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
22 remaining allegations in this paragraph of the Complaint.

23 **Response to First Cause of Action: Negligence**

24 Defendants incorporate by reference their responses to each paragraph of Plaintiff's
25 Complaint as if fully set forth herein.

26 Defendants state that this paragraph of the Complaint contains legal contentions to which
27 no response is required. To the extent that a response is deemed required, Defendants admit that
28 they had duties as are imposed by law but deny having breached such duties. Defendants state

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1 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
2 prescribing information. Defendants state that the potential effects of Celebrex® were and are
3 adequately described in its FDA-approved prescribing information, which was at all times
4 adequate and comported with applicable standards of care and law. Defendants deny any
5 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

6 Defendants state that this paragraph of the Complaint contains legal contentions to which
7 no response is required. To the extent that a response is deemed required, Defendants admit that
8 they had duties as are imposed by law but denies having breached such duties. Defendants state
9 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
10 prescribing information. Defendants state that the potential effects of Celebrex® were and are
11 adequately described in its FDA-approved prescribing information, which was at all times
12 adequate and comported with applicable standards of care and law. Defendants deny any
13 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

14 Defendants state that this paragraph of the Complaint contains legal contentions to which
15 no response is required. To the extent that a response is deemed required, Defendants admit that
16 they had duties as are imposed by law but deny having breached such duties. Defendants are
17 without knowledge or information sufficient to form a belief as to the truth of the allegations in
18 this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny
19 the same. Defendants state that Celebrex® was and is safe and effective when used in
20 accordance with its FDA-approved prescribing information. Defendants state that the potential
21 effects of Celebrex® were and are adequately described in its FDA-approved prescribing
22 information, which was at all times adequate and comported with applicable standards of care
23 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this
24 paragraph of the Complaint, including all subparts.

25 Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
27 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Celebrex® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 Defendants are without knowledge or information sufficient to form a belief as to the
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
14 effective when used in accordance with its FDA-approved prescribing information. Defendants
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-
16 approved prescribing information, which was at all times adequate and comported with
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
18 remaining allegations in this paragraph of the Complaint.

19 Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition
21 or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny any
22 wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the
23 remaining allegations in this paragraph of the Complaint.

24 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
25 damages, and deny the remaining allegations in this paragraph of the Complaint.

26 Answering the unnumbered paragraph following Paragraph 92 of the Complaint,
27 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages,
28 and deny the remaining allegations in this paragraph of the Complaint.

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Response to Second Cause of Action: Strict Liability

Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably
4 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

5 Defendants state that Celebrex® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants state that the potential effects of
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
10 remaining allegations in this paragraph of the Complaint.

11 Defendants state that Celebrex® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the
16 remaining allegations in this paragraph of the Complaint.

17 Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
19 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-
22 approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
24 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damages, and deny the
25 remaining allegations in this paragraph of the Complaint.

26 Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.

2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
7 effective when used in accordance with its FDA-approved prescribing information. Defendants
8 state that the potential effects of Celebrex® were and are adequately described in its FDA-
9 approved prescribing information, which was at all times adequate and comported with
10 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
11 Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this
12 paragraph of the Complaint.

13 Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Celebrex® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint

27 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
28 damages, and deny the remaining allegations in this paragraph of the Complaint.

1 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
2 damages, and deny the remaining allegations in this paragraph of the Complaint.

3 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
4 damages, and deny the remaining allegations in this paragraph of the Complaint.

5 **Response to Third Cause of Action: Breach of Express Warranty**

6 Defendants incorporate by reference their responses to each paragraph of Plaintiff's
7 Complaint as if fully set forth herein.

8 Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
10 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
11 effective when used in accordance with its FDA-approved prescribing information. Defendants
12 state that the potential effects of Celebrex® were and are adequately described in its FDA-
13 approved prescribing information, which was at all times adequate and comported with
14 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
15 information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the
16 Complaint.

17 Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
19 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-
22 approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
24 information for Celebrex®. Defendants deny any wrongful conduct and deny the remaining
25 allegations in this paragraph of the Complaint, including all subparts.

26 Defendants admit to providing FDA-approved prescribing information for Celebrex®.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

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1 Defendants state that Celebrex® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
6 the Complaint.

7 Defendants state that Celebrex® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
12 the Complaint.

13 Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
15 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendants admit to providing FDA-approved prescribing information for Celebrex®.
19 Defendants deny the remaining allegations in this paragraph of the Complaint.

20 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
21 damages, and deny the remaining allegations in this paragraph of the Complaint.

22 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
23 damages, and deny the remaining allegations in this paragraph of the Complaint.

24 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
25 damages, and deny the remaining allegations in this paragraph of the Complaint.

26 **Response to Fourth Cause of Action: Breach of Implied Warranty**

27 Defendants incorporate by reference their responses to each paragraph of Plaintiff's
28 Complaint as if fully set forth herein.

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1 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and
2 co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
3 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
4 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
5 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
6 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
7 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
8 paragraph of the Complaint.

9 Defendants state that Celebrex® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendants state that the potential effects of
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.

13 Defendants admit to providing FDA-approved prescribing information for Celebrex®.

14 Defendants deny the remaining allegations in this paragraph of the Complaint.

15 Defendants state that Celebrex® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants state that the potential effects of
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.

19 Defendants deny the remaining allegations in this paragraph of the Complaint.

20 Defendants state that this paragraph of the Complaint contains legal contentions to which
21 no response is required. To the extent that a response is deemed required, Defendants state that
22 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
23 prescribing information. Defendants state that the potential effects of Celebrex® were and are
24 adequately described in its FDA-approved prescribing information, which was at all times
25 adequate and comported with applicable standards of care and law. Defendants deny any
26 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

27 Defendants are without knowledge or information sufficient to form a belief as to the
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription
2 medication which is approved by the FDA for the following indications: (1) for relief of the signs
3 and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis
4 in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary
5 dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
6 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery);
7 (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and
8 symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants
9 deny the remaining allegations in this paragraph of the Complaint.

10 Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
12 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
13 effective when used in accordance with its FDA-approved prescribing information. Defendants
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-
15 approved prescribing information, which was at all times adequate and comported with
16 applicable standards of care and law. Defendants admit to providing FDA-approved prescribing
17 information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the
18 Complaint.

19 Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
21 Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case,
22 Celebrex® was expected to reach users and consumers without substantial change from the time
23 of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

24 Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
26 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
27 effective when used in accordance with its FDA-approved prescribing information. Defendants
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

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1 approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
3 remaining allegations in this paragraph of the Complaint.

4 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
5 damages, and deny the remaining allegations in this paragraph of the Complaint.

6 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
7 damages, and deny the remaining allegations in this paragraph of the Complaint.

8 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
9 damages, and deny the remaining allegations in this paragraph of the Complaint.

10 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

11 Defendants incorporate by reference their responses to each paragraph of Plaintiff's
12 Complaint as if fully set forth herein.

13 Defendants state that this paragraph of the Complaint contains legal contentions to which
14 no response is required. To the extent that a response is deemed required, Defendants admit that
15 they had duties as are imposed by law but deny having breached such duties. Defendants state
16 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved
17 prescribing information. Defendants state that the potential effects of Celebrex® were and are
18 adequately described in its FDA-approved prescribing information, which was at all times
19 adequate and comported with applicable standards of care and law. Defendants deny any
20 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

21 Defendants state that Celebrex® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendants state that the potential effects of
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
26 the Complaint, including all subparts.

27 Defendants state that Celebrex® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
4 the Complaint, including all subparts.

5 Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
7 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
8 effective when used in accordance with its FDA-approved prescribing information. Defendants
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-
10 approved prescribing information, which was at all times adequate and comported with
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
12 remaining allegations in this paragraph of the Complaint, including all subparts.

13 Defendants state that Celebrex® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Celebrex® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
18 the Complaint.

19 Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
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9 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
10 remaining allegations in this paragraph of the Complaint.

11 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
12 damages, and deny the remaining allegations in this paragraph of the Complaint.

13 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
14 damages, and deny the remaining allegations in this paragraph of the Complaint.

15 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
16 damages, and deny the remaining allegations in this paragraph of the Complaint.

17 **Response to Sixth Cause of Action: Unjust Enrichment**

18 Defendants incorporate by reference their responses to each paragraph of Plaintiff's
19 Complaint as if fully set forth herein.

20 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and
21 co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by
22 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
23 admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,
24 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States
25 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
26 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
27 paragraph of the Complaint.

28 Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
2 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this
3 paragraph of the Complaint.

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5 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
6 Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this
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21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
23 remaining allegations in this paragraph of the Complaint.

24 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or
25 damages, and deny the remaining allegations in this paragraph of the Complaint.

26 **Response to Prayer For Relief**

27 Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,”
28 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages,

1 and deny the remaining allegations this paragraph of the Complaint, including all subparts.

2 **III.**

3 **GENERAL DENIAL**

4 Defendants deny the allegations and/or legal conclusions set forth in Plaintiff's
5 Complaint that have not been previously admitted, denied, or explained.

6 **IV.**

7 **AFFIRMATIVE DEFENSES**

8 Defendants reserve the right to rely upon any of the following or additional defenses to
9 claims asserted by Plaintiff to the extent that such defenses are supported by information
10 developed through discovery or evidence at trial. Defendants affirmatively show that:

11 The Complaint fails to state a claim upon which relief can be granted

12 Celebrex® is a prescription medical product. The federal government has preempted the
13 field of law applicable to the labeling and warning of prescription medical products.
14 Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable
15 federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon
16 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
17 and violate the Supremacy Clause of the United States Constitution.

18 At all relevant times, Defendants provided proper warnings, information and instructions
19 for the drug in accordance with generally recognized and prevailing standards in existence at the
20 time.

21 At all relevant times, Defendants' warnings and instructions with respect to the use of
22 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of
23 knowledge at the time the drug was manufactured, marketed and distributed.

24 Plaintiff's action is time-barred as it is filed outside of the time permitted by the
25 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

26 Plaintiff's action is barred by the statute of repose.

27 If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the
28 Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's

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1 damages, if any, are barred or reduced by the doctrines of comparative fault and contributory
2 negligence and by the failure to mitigate damages.

3 The proximate cause of the loss complained of by Plaintiff is not due to any acts or
4 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part
5 of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
6 liable in any way.

7 The acts and/or omissions of unrelated third parties as alleged constituted independent,
8 intervening causes for which Defendants cannot be liable.

9 Any injuries or expenses incurred by Plaintiff were not caused by Celebrex®, but were
10 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act
11 of God.

12 Defendants affirmatively deny that they violated any duty owed to Plaintiff.

13 A manufacturer has no duty to warn patients or the general public of any risk,
14 contraindication, or adverse effect associated with the use of a prescription medical product.
15 Rather, the law requires that all such warnings and appropriate information be given to the
16 prescribing physician and the medical profession, which act as a “learned intermediary” in
17 determining the use of the product. Celebrex® is a prescription medical product, available only
18 on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff’s
19 treating and prescribing physicians.

20 The product at issue was not in a defective condition or unreasonably dangerous at the
21 time it left the control of the manufacturer or seller.

22 Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit
23 for its intended use and the warnings and instructions accompanying Celebrex® at the time of
24 the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

25 Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the
26 Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable
27 standard of care.

28 If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the

1 Complaint, the same were caused by the unforeseeable alteration, change, improper handling,
2 abnormal use, or other unforeseeable misuse of Celebrex® by persons other than Defendants or
3 persons acting on its behalf after the product left the control of Defendants.

4 Plaintiff's alleged damages were not caused by any failure to warn on the part of
5 Defendants.

6 Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
7 conditions unrelated to Celebrex®.

8 Plaintiff knew or should have known of any risk associated with Celebrex®; therefore,
9 the doctrine of assumption of the risk bars or diminishes any recovery.

10 Plaintiff is barred from recovering against Defendants because Plaintiff's claims are
11 preempted in accordance with the Supremacy Clause of the United States Constitution and by the
12 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

13 Plaintiff's claims are barred in whole or in part under the applicable state law because the
14 subject pharmaceutical product at issue was subject to and received pre-market approval by the
15 Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

16 The manufacture, distribution and sale of the pharmaceutical product referred to in
17 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,
18 and Plaintiff's causes of action are preempted.

19 Plaintiff's claims are barred in whole or in part by the deference given to the primary
20 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at
21 issue under applicable federal laws, regulations, and rules.

22 Plaintiff's claims are barred in whole or in part because there is no private right of action
23 concerning matters regulated by the Food and Drug Administration under applicable federal
24 laws, regulations, and rules.

25 Plaintiff's claims are barred in whole or in part because Defendants provided adequate
26 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of
27 Comment j to Section 402A of the Restatement (Second) of Torts.

28 Plaintiff's claims are barred or limited to a product liability failure to warn claim because

1 Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement
2 (Second) of Torts § 402A, Comment k.

3 Plaintiff's claims are barred in whole or in part because the subject pharmaceutical
4 product at issue "provides net benefits for a class of patients" within the meaning of Comment f
5 to § 6 of the Restatement (Third) of Torts: Products Liability.

6 Plaintiff's claims are barred under § 4, *et seq.*, of the Restatement (Third) of Torts:
7 Products Liability.

8 To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts
9 sufficient under the law to justify an award of punitive damages.

10 The imposition of punitive damages in this case would violate Defendants' rights to
11 procedural due process under the Fourteenth Amendment of the United States Constitution,
12 Article I, § 17 of the Constitution of the States of Minnesota, and the Constitution of the State of
13 Alabama, and would additionally violate Defendants' right to substantive due process under the
14 Fourteenth Amendment of the United States Constitution.

15 Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and
16 Fourteenth Amendments to the United States Constitution and are subject to all provisions of
17 Minnesota and Alabama law, including, but not limited to, Minn. Stat. § 549.191 (2006).

18 The imposition of punitive damages in this case would violate the First Amendment to
19 the United States Constitution.

20 Plaintiff's punitive damage claims are preempted by federal law.

21 In the event that reliance was placed upon Defendants' nonconformance to an express
22 representation, this action is barred as there was no reliance upon representations, if any, of
23 Defendants.

24 Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance
25 to any express representation.

26 To the extent that Plaintiff's claims are based on a theory providing for liability without
27 proof of causation, the claims violate Defendants' rights under the United States Constitution.

28 Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and

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1 labeling with respect to the subject pharmaceutical products were not false or misleading and,
2 therefore, constitute protected commercial speech under the applicable provisions of the United
3 States Constitution.

4 To the extent that Plaintiff seeks punitive damages for the conduct which allegedly
5 caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable
6 law or statute or, in the alternative, are unconstitutional insofar as they violate the due process
7 protections afforded by the United States Constitution, the excessive fines clause of the Eighth
8 Amendment of the United States Constitution, the Commerce Clause of the United States
9 Constitution, and the Full Faith and Credit Clause of the United States Constitution and the
10 Constitutions of the States of Minnesota and Alabama. Any law, statute, or other authority
11 purporting to permit the recovery of punitive damages in this case is unconstitutional, facially
12 and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient
13 standards to guide and restrain the jury's discretion in determining whether to award punitive
14 damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate
15 advance notice as to what conduct will result in punitive damages; (3) permits recovery of
16 punitive damages based on out-of-state conduct, conduct that complied with applicable law, or
17 conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits
18 recovery of punitive damages in an amount that is not both reasonable and proportionate to the
19 amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5)
20 permits jury consideration of net worth or other financial information relating to Defendants; (6)
21 lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of
22 any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review
23 of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent,
24 including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO*
25 *Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc.*
26 *v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408
27 (2003).

28 The methods, standards, and techniques utilized with respect to the manufacture, design,

1 and marketing of Celebrex®, if any, used in this case, included adequate warnings and
2 instructions with respect to the product's use in the package insert and other literature, and
3 conformed to the generally recognized, reasonably available, and reliable state of the knowledge
4 at the time the product was marketed.

5 The claims asserted in the Complaint are barred because Celebrex® was designed, tested,
6 manufactured and labeled in accordance with the state-of-the-art industry standards existing at
7 the time of the sale.

8 If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
9 and belief, such injuries and losses were caused by the actions of persons not having real or
10 apparent authority to take said actions on behalf of Defendants and over whom Defendants had
11 no control and for whom Defendants may not be held accountable.

12 The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
13 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
14 intended, and was distributed with adequate and sufficient warnings.

15 Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,
16 waiver, and/or estoppel.

17 Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-
18 existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses,
19 subsequent medical conditions or natural courses of conditions of Plaintiff, and were
20 independent of or far removed from Defendants' conduct.

21 The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
22 did not proximately cause injuries or damages to Plaintiff.

23 The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did
24 not incur any ascertainable loss as a result of Defendants' conduct.

25 The claims asserted in the Complaint are barred, in whole or in part, because the
26 manufacturing, labeling, packaging, and any advertising of the product complied with the
27 applicable codes, standards and regulations established, adopted, promulgated or approved by
28 any applicable regulatory body, including but not limited to the United States, any state, and any

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1 agency thereof.

2 The claims must be dismissed because Plaintiff would have taken Celebrex® even if the
3 product labeling contained the information that Plaintiff contends should have been provided.

4 The claims asserted in the Complaint are barred because the utility of Celebrex®
5 outweighed its risks.

6 Plaintiff's damages, if any, are barred or limited by the payments received from collateral
7 sources.

8 Defendants' liability, if any, can only be determined after the percentages of
9 responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if
10 any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants
11 and each and every other person whose fault could have contributed to the alleged injuries and
12 damages, if any, of Plaintiff.

13 Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the
14 common law gives deference to discretionary actions by the United States Food and Drug
15 Administration under the Federal Food, Drug, and Cosmetic Act.

16 The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
17 is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act
18 ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's
19 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
20 FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and
21 with the specific determinations by FDA specifying the language that should be used in the
22 labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the
23 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
24 United States.

25 Plaintiff's misrepresentation allegations are not stated with the degree of particularity
26 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

27 Plaintiff's claim for punitive damages is barred pursuant to Minn. Stat. § 549.191.

28 Defendants reserve the right to supplement their assertion of defenses as they continue

1 with their factual investigation of Plaintiff's claims.

2 V.

3 **JURY DEMAND**

4 Defendants hereby demand a trial by jury.

5 VI.

6 **PRAYER**

7 WHEREFORE, Defendants pray that Plaintiff takes nothing by this suit, that
8 Defendants be discharged with their costs expended in this matter, and for such other and further
9 relief to which they may be justly entitled.

10
11 Dated: May 23, 2008

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12
13 _____/s/
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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

NETRA THOMAS,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
G.D. SEARLE LLC and MONSANTO
COMPANY,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-02110-CRB

) **RULE 7.1 STATEMENT**

) **JURY TRIAL DEMANDED**

Pursuant to Federal Rule of Civil Procedure 7.1, Defendants Pfizer Inc. ("Pfizer"),
Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC ("Searle") submit this their
Corporate Disclosure Statement. Defendants Pfizer, Pharmacia and Searle state:

1. Defendant Pfizer Inc. does not have any parent corporations, and no publicly traded company owns 10% or more of Pfizer Inc.'s stock.

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2. Defendant Pharmacia Corporation is a wholly-owned subsidiary of Defendant Pfizer Inc.
3. Defendant G.D. Searle LLC is a limited liability company whose sole member is Pharmacia & Upjohn Company LLC, which is a limited liability company whose sole member is Pharmacia & Upjohn LLC, which is a limited liability company whose sole member is Pharmacia Corporation.

May 23, 2008

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